

EPA Reg. No. 70299-2
Vol. 1
(to Notice of Registration)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
(7511C) 401 M St., S.W.
Washington, D.C. 20460

EPA Reg.
Number:

70299-2

Date of Issuance:

JUN 22 1999

NOTICE OF PESTICIDE:

 X Registration
_____ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

Oximate Broad Spectrum
Bactericide/Fungicide

Name and Address of Registrant (include ZIP Code):

Biosafe Systems
80 Commerce Street, Glastonberry, CT 06033

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This registration does not eliminate the need for continual reassessment of the pesticide. If EPA determines at any time, that additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under section 3(c)(2)(B) of FIFRA.

This product is registered in accordance with FIFRA section 3(c)(5) and is subject to the following terms and conditions:

1. Make the following modifications to your label before you release your product for shipment:

a) Change the EPA File Symbol 70299-E to EPA Reg. No. 70299-2

2. Submit five (5) copies of the revised final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

A stamped copy of the label is enclosed for your records.

Signature of Approving Official:

Joseph L. Anderson
see next page

Date:

JUN 22 1999

EPA Form 8570-6

CONCURRENCES

SYMBOL	7511C	7511C					
SURNAME	BALL	Reilly					
DATE	6/17/99	6/21/99					

A-79 ENCLOSURE

Final printed labeling is defined as that labeling which will accompany the pesticide product to market, and includes not only the container label, but also all accompanying technical information, brochures, etc.

Final printed labeling for the Agency's files should be of a size that can be stored conveniently in 8 1/2 x 11 inch files. Labels may be mounted or photoreduced to meet the size requirements provided the printing is legible and is of microfilm reproduction quality. Should photo reduction make any of the text illegible, the text must be typed out on an accompanying sheet of paper.

PASTE-ON LABELING: This should be submitted as is, unless it requires photo reduction.

SCREEN PRINTED LABELING: These labels should be printed by taping paper on the container as it goes through the printing process. The actual container should not be submitted.

EMBOSSSED LABELING: These labels should be photocopied.

UNUSUAL SIZE LABELING: Large bags or boxes must be photoreduced, either the entire label on one reduction or in sections so that each section is 8 1/2 x 11 inches.

Type Size Requirements for 3 Front Panel Headings

<u>Size of front panel square inches</u>	<u>Minimum type size for "RESTRICTED USE PESTICIDE" (if required) and Signal Word in capital letters</u>	<u>Minimum type for "Storage and Disposal" heading & "Keep Out of Reach of Children" warning</u>
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Oxidate™

Broad Spectrum Bactericide / Fungicide

- * Preventative treatment for growing plants, fruits, nuts and vegetables.
- * A treatment for the prevention and control of plant pathogenic diseases in field grown crops, commercial greenhouses, and storage sites.

FOR AGRICULTURAL AND COMMERCIAL USE ONLY

ACTIVE INGREDIENT:

Hydrogen Dioxide..... 27%

INERT INGREDIENTS:..... 73%

TOTAL:..... 100%

KEEP OUT OF REACH OF CHILDREN

DANGER - PELIGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand this label, find someone to explain it to you in detail.)

STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get immediate medical attention.

IF ON SKIN: Remove contaminated clothing and wash affected areas with plenty of soap and water. Get immediate medical attention.

IF SWALLOWED: Call a physician or poison control center immediately. Drink large quantities of water. Do not induce vomiting or give anything by mouth to an unconscious person. Avoid alcohol. Note to physician: Probable mucosal damage may contraindicate the use of gastric lavage.

IF INHALED: Remove victim to fresh air. Get immediate medical attention.

See side panel for additional precautionary statements.

Sold by: BioSafe Systems, 80 Commerce Street, Glastonbury, CT 06033

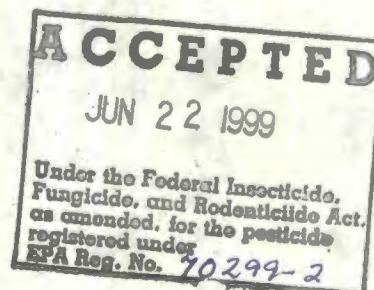
EPA Registration No. 70299-E

EPA Establishment No. 68660-TX-01

Net Contents: 2.5 gallons

Oxidate Broad Spectrum Bactericide/Fungicide

Last revised February 11, 1999



PRECAUTIONARY STATEMENTS

HAZARDS TO HUMAN AND DOMESTIC ANIMALS

CORROSIVE: Concentrate causes irreversible eye damage. Concentrate may be fatal if swallowed. Concentrate causes skin irritation or temporary discoloration on exposed skin. Do not breathe vapor of concentrate. Do not get concentrate in eyes, on skin or on clothing.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

When handling concentrate wear protective eyewear (goggles or face shield) and rubber gloves. Applicators and handlers must wear coveralls over long-sleeved shirt, long pants, and chemical resistant footwear plus socks. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water.

USER SAFETY RECOMMENDATIONS

Users should wash hands thoroughly with soap and water before eating, drinking, chewing gum, using tobacco or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

FOR TERRESTRIAL USES. Keep out of lakes, ponds and streams. This pesticide is toxic to birds and fish. Do not apply directly to water, or to areas where surface water is present or to inter-tidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of wash waters.

This product is highly toxic to bees and other beneficial insects exposed to direct contact on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area. Do not apply this product or allow it to drift to crops where beneficials are part of an Integrated Pest Management strategy.

PHYSICAL AND CHEMICAL HAZARDS

Strong oxidizing agent. **Corrosive.** Do not use in concentrated form. Mix only with water in accordance with label instructions. Never bring concentrate in contact with other pesticides, cleaners or oxidative agents.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

Oxidate Broad Spectrum Bactericide/Fungicide
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AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about Personal Protective Equipment (PPE) and Restricted-Entry Interval (REI). The requirements in this box only apply to the uses of this product that are covered by the Worker Protection Standard.

There is a restricted entry of zero (0) hours for this product.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Store in original containers in a cool, well-vented area, away from direct sunlight. Do not allow product to become overheated in storage. This may cause increased degradation of the product, which will decrease product effectiveness. In case of spill, flood area with large quantities of water. Do not store in a manner where cross-contamination with other pesticides or fertilizers could occur.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Open dumping is prohibited. If wastes cannot be disposed of according to label directions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

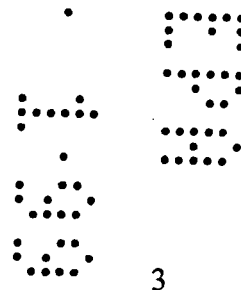
CONTAINER DISPOSAL: Triple rinses (or equivalent). Then offer for recycling or dispose in a sanitary landfill, or incineration, if allowed by state and local authorities by burning, stay out of smoke.

DIRECTIONS FOR USE:

- * Oxidate™ works best when diluted with water containing low levels of organic or inorganic materials, and with water having a neutral pH. Thoroughly rinse out tank with water before mixing concentrate. Oxidate™ will readily mix with clean, neutral water and does not require agitation.
- * Oxidate™ should not be combined or mixed with any other pesticide or fertilizer.
- * Oxidate™ is formulated with a minimal amount of surfactant for plants having waxy or hairy surfaces. Additional surfactant may be added, if needed.

Oxidate™ works by surface contact with the plants and materials being treated. It is important to ensure that all surfaces are thoroughly wetted. Oxidate™ does not produce any visible residue, distinct odor or deleterious effects to plants when used in accordance with label directions. Do not use at higher than recommended dilution rates as leaf burn may result.

Oxidate Broad Spectrum Bactericide/Fungicide
Last revised January 28, 1999



Do not apply this product through any irrigation system unless directed by the label; refer to Chemigation Directions for Use.

Use Rates and Directions:

Pre-Plant Dip Treatment -

Use Oxidate™ for the control of damping-off, root disease and stem rot disease caused by *Pythium*, *Phytophthora*, *Rhizoctonia*, *Fusarium* or *Thielaviopsis*, on seeds, seedlings, bulbs, or cuttings.

- 1) Mix 64-fl. oz. per 50 gallons of water.
- 2) Immerse plants or cuttings; remove and allow to drain. Do not rinse.

Soil Drench -

Oxidate™ is effective for the control of soil borne plant diseases such as *Pythium*, *Phytophthora*, *Rhizoctonia*, *Thielaviopsis* or *Fusarium*. Use as a soil drench at the time of seeding or transplanting, as well as a periodic drench throughout the plant's life. Oxidate™ can also be used on potting soil and growing mediums prior to planting.

- 1) Mix 1¼ fl. oz. Oxidate™ per gallon of clean water.
- 2) Apply to soil or growing media to the point of saturation.
- 3) Wait fifteen minutes before planting or watering.

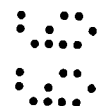
Foliar Spray Treatments for field grown crops, crops grown in commercial greenhouses or crops grown in other similar sites -

Oxidate™ works immediately on contact with any plant surface for control. Good coverage and wetting of the foliage is necessary.

Crops	Disease	Dilution Rate	Application Rate	Directions
Beans	Anthracnose Downy Mildew Powdery Mildew Rust	1:100	128 oz. Oxidate per 100 gallons of water; apply 50-100 gallons of spray solution per acre.	Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
		1:100 - 1:300	40-128 oz. Oxidate per 100 gallons of water; apply 50-100 gallons of spray solution per acre.	Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5-day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5-day interval spray cycle until harvest.
Broccoli Cauliflower Cabbage	Alternaria Leaf Spot Downy Mildew Powdery Mildew	1:100	128 oz. Oxidate per 100 gallons of water; apply 50-100 gallons of spray solution per acre.	Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
		1:100 - 1:300	40-128 oz. Oxidate per 100 gallons of water; apply 50-100 gallons of spray solution per acre.	Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5-day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5-day interval spray cycle until harvest.

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Crops	Disease	Dilution Rate	Application Rate	Directions
Citrus	Rust Scab Powdery Mildew Brown Rot Phytophthora	1:100	128 oz. Oxidate per 100 gallons of water; apply 50–100 gallons of spray solution per acre.	Pre-Bloom: Begin applications at ¼ - ½ inch green tip and continue on a five to seven day schedule through bloom.
		1:100 – 1:300	40–128 oz. Oxidate per 100 gallons of water; apply 50–100 gallons of spray solution per acre.	Curative: Spray diseased trees using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals. Preventive: Spray once a week until harvest.
Cucurbits	Alternaria Anthracnose Downy Mildew Powdery Mildew Pythium Rot	1:100	128 oz. Oxidate per 100 gallons of water; apply 50–100 gallons of spray solution per acre.	Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
		1:100 – 1:300	40–128 oz. Oxidate per 100 gallons of water; apply 50–100 gallons of spray solution per acre.	Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5-day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5-day interval spray cycle until harvest.
Onions	Botrytis Downy Mildew Powdery Mildew	1:100	128 oz. Oxidate per 100 gallons of water; apply 50–100 gallons of spray solution per acre.	Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
		1:100 – 1:300	40–128 oz. Oxidate per 100 gallons of water; apply 50–100 gallons of spray solution per acre.	Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5-day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5-day interval spray cycle until harvest.
Peppers	Anthracnose Phytophthora Blight Powdery Mildew	1:100	128 oz. Oxidate per 100 gallons of water; apply 50–100 gallons of spray solution per acre.	Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
		1:100 – 1:300	40–128 oz. Oxidate per 100 gallons of water; apply 50–100 gallons of spray solution per acre.	Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5-day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5-day interval spray cycle until harvest.
Potatoes	Early Blight Late Blight	1:100	128 oz. Oxidate per 100 gallons of water; apply 50–100 gallons of spray solution per acre.	Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
		1:100 – 1:300	40–128 oz. Oxidate per 100 gallons of water; apply 50–100 gallons of spray solution per acre.	Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5-day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5-day interval spray cycle until harvest.

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Crops	Disease	Dilution Rate	Application Rate	Directions
Seed Potatoes	Fusarium	1: 50	2.5 oz. Oxidate per gallon of water.	Dip whole or cut tubers into tank of working solution. Let soak for a period of five minutes before removing seed pieces.
Tomatoes	Anthraxnose Cladosporium Mold Early Blight Late Blight Powdery Mildew	1:100 1:100 - 1:300	128 oz. Oxidate per 100 gallons of water; apply 50-100 gallons of spray solution per acre. 40-128 oz. Oxidate per 100 gallons of water; apply 50-100 gallons of spray solution per acre.	Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals. Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5-day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5-day interval spray cycle until harvest.
Apples	Rusts Scab Powdery Mildew	1:100 1: 100	128 oz. Oxidate per 100 gallons of water; apply 50-100 gallons of spray solution per acre.	Curative: Spray diseased trees using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals. Pre-Bloom: Begin applications at ¼ - ½ inch green tip and continue on a five to seven day schedule through bloom.
Filberts	Eastern Filbert Blight Bacterial Blight	1:100 1: 100	128 oz. Oxidate per 100 gallons of water; apply 50-100 gallons of spray solution per acre.	Curative: Spray diseased trees using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals. Pre-Bloom: Begin applications at ¼ - ½ inch green tip and continue on a five to seven day schedule through bloom.
Bananas	Sigatoka	1:100 1:100 - 1:300	128 oz. Oxidate per 100 gallons of water; apply 50-100 gallons of spray solution per acre. 40-128 oz. Oxidate per 100 gallons of water; apply 50-100 gallons of spray solution per acre.	Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals. Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5-day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5-day interval spray cycle until harvest.
Grapes	Black Rot Downy Mildew Powdery Mildew	1:100 1:100 - 1:300	128 oz. Oxidate per 100 gallons of water; apply 50-100 gallons of spray solution per acre. 40-128 oz. Oxidate per 100 gallons of water; apply 50-100 gallons of spray solution per acre.	Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals. Preventive: Begin when shoots are small. Apply first three treatments at 1:100, for 5-day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5-day interval spray cycle until harvest.

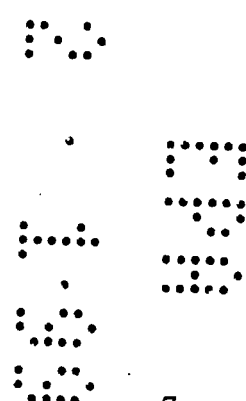
Crops	Disease	Dilution Rate	Application Rate	Directions
Stone Fruits Peaches Plums Cherries Nectarines Prunes	Downy Mildew Powdery Mildew Brown Rot	1:100	128 oz. Oxidate per 100 gallons of water; apply 50–100 gallons of spray solution per acre.	Pre-Bloom: Begin applications at ¼ - ½ inch green tip and continue on a five to seven day schedule through bloom. Curative: Spray diseased trees using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.

Spray Treatments for newly harvested potatoes before storage –

Crops	Disease	Dilution Rate	Application Rate	Directions
Potatoes	Fusarium Tuber Rot Bacteria Soft Rot Silver Scurf	1: 50 – 1: 100	2.5 – 1.25 oz. Oxidate per gallon of water.	Spray diluted solution on tuber to runoff to achieve full and even coverage. Additional surfactant can be added as needed to aid in sticking. Use 1 to 2 gallons of water per ton of potatoes.

Direct injection into humidification water for postharvest potatoes in storage –

Crops	Disease	Dilution Rate	Application Rate	Directions
Potatoes	Fusarium Tuber Rot Bacteria Soft Rot Silver Scurf	1:100 – 1:300	2.25 – 1.5 oz. Oxidate per gallon of water.	Inject concentrate into makeup water used in humidification of postharvest potatoes in storage.



Chemigation Directions for Use

General Requirements:

- 1) Apply this product only through a sprinkler including a center pivot, lateral move, end tow, side wheel roll, traveler, solid set, hand move, flood basin or drip trickle irrigation system. Do not apply this product through any other type of irrigation system.
- 2) Crop injury or lack of effectiveness can result from non-uniform distribution of treated water.
- 3) Ensure that the irrigation system used is properly calibrated and if you have questions, call the state extension service or the equipment manufacturer.
- 4) Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless proper safety devices for public water systems are in place. Read label for instructions.
- 5) A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make any necessary adjustments should the need arise.

Specific Requirements:

- 1) Public water supply means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of 25 individuals daily at least 60 days throughout the year.
- 2) Chemigation systems connected to the public water systems must contain a functional, reduced-pressure zone (RPZ), backflow preventer or the functional equivalent in the water supply upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top of the overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.
- 3) The pesticide injection pipeline must contain a functional, automatic, quick closing check valve to prevent the flow of liquid back towards the injector.
- 4) The pesticide injection pipeline must contain a functional, normally closed, solenoid, operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being drawn from the supply tank when the irrigation system is either automatically or manually shut down.
- 5) The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.
- 6) Systems must use a metering pump, such as a positive displacement injection pump, or equivalent, effectively designed and constructed of materials that are compatible with pesticides and capable of being filled with a system interlock.
- 7) Do not apply when wind speed favors drift beyond the area intended for treatment.

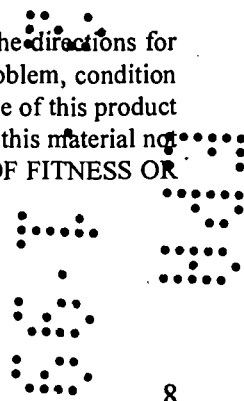
Application Instructions:

- 1) Remove scale, pesticide residues, and other foreign matter from the chemical supply tank and entire injector system. Flush with clean water. Failure to provide a clean tank, void of scale or residues may cause product to lose effectiveness or strength.
- 2) Determine the treatment rates as indicated in the directions for use and make proper dilutions.
- 3) Prepare a solution in the chemical tank by filling the tank with the required water and then adding product as required. The product will immediately go into suspension without any required agitation.
- 4) Oxidate should not be applied in conjunction with any other pesticides or fertilizers; this may cause reduced performance of the product and should be avoided.

WARRANTY

This material conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing, method of application, weather, watering practices, nature of soil, potting medium, disease problem, condition of crop, incompatibility with other chemicals, pre-existing conditions and other conditions influencing the use of this product are beyond the control of the seller. Buyer assumes all risks associated with the use, storage, or handling of this material not in strict accordance with directions given herewith. NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY IS MADE.

Oxidate Broad Spectrum Bactericide/Fungicide
Last revised January 28, 1999





U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
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Number:
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 Reregistration

(under FIFRA, as amended)

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Name of Pesticide Product:
Oxidate Broad Spectrum
Bactericide/Fungicide

Name and Address of Registrant (include ZIP Code):

Biosafe Systems
80 Commerce Street, Glastonberry, CT 06033

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This registration does not eliminate the need for continual reassessment of the pesticide. If EPA determines at any time, that additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under section 3(c)(2)(B) of FIFRA.

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1. Make the following modifications to your label before you release your product for shipment:
 - a) Change the EPA File Symbol 70299-E to EPA Reg. No. 70299-2
2. Submit five (5) copies of the revised final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

A stamped copy of the label is enclosed for your records.

Signature of Approving Official:

Date:

JUN 22 1999

EPA Form 8570-6

6/17/99

Date

ROUTING AND TRANSMITTAL SLIP

TO: (Name, office symbol, room number,
building, Agency/Post)

Initials

Date

1. *Sheryl (concurance)* SKR 6/21/992. *Tanet (signature)* JPA 6/22

RECEIVED

4. JUN 21 1999

5. #420

OPP/BPPD

Action	File	Note and Return
Approval	For Clearance	Per Conversation
As Requested	For Correction	Prepare Reply
Circulate	For Your Information	See Me
Comment	Investigate	Signature
Coordination	Justify	

REMARKS

This request is for "Oxidate" -
for food use, based on revised, or reassessed
H₂O₂ tolerance Exemption. Trial rule
to be published June 21, so I have
been informed by the Federal Register office.
So it should be dated ^{earlier} ~~no later~~ than
June 21. The registrant, Biosafe, is very
eager, as you can see - and we have tried
to accommodate him; I plan to write an update
to the RED (Published) in 1/93.
DO NOT use this form as a RECORD of approvals, concurrences, disposals,
clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)

Room No.—Bldg.

Phone No.

308-8717

5041-103

OPTIONAL FORM 14 (Rev. 1-94)

*U.S. Government Printing Office: 1995 — 387-722/20018

Prescribed by GSA

Oxide™

Broad Spectrum Bactericide / Fungicide

- * Preventative treatment for growing plants, fruits, nuts and vegetables.
- * A treatment for the prevention and control of plant pathogenic diseases in field grown crops, commercial greenhouses, and storage sites.

FOR AGRICULTURAL AND COMMERCIAL USE ONLY

ACTIVE INGREDIENT:

Hydrogen Dioxide..... 27%

INERT INGREDIENTS:..... 73%

TOTAL:..... 100%

KEEP OUT OF REACH OF CHILDREN

ANGER - PELIGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.

(If you do not understand this label, find someone to explain it to you in detail.)

STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get immediate medical attention.

IF ON SKIN: Remove contaminated clothing and wash affected areas with plenty of soap and water. Get immediate medical attention.

IF SWALLOWED: Call a physician or poison control center immediately. Drink large quantities of water. Do not induce vomiting or give anything by mouth to an unconscious person. Avoid alcohol.

Note to physician: Probable mucosal damage may contraindicate the use of gastric lavage.

IF INHALED: Remove victim to fresh air. Get immediate medical attention.

See side panel for additional precautionary statements.

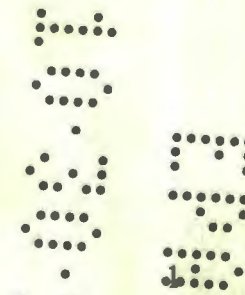
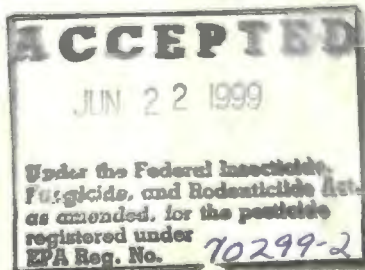
Sold by: BioSafe Systems, 80 Commerce Street, Glastonbury, CT 06033

EPA Registration No. 70299-E

EPA Establishment No. 68660-TX-01

Net Contents: 2.5 gallons

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMAN AND DOMESTIC ANIMALS

CORROSIVE: Concentrate causes irreversible eye damage. Concentrate may be fatal if swallowed. Concentrate causes skin irritation or temporary discoloration on exposed skin. Do not breathe vapor of concentrate. Do not get concentrate in eyes, on skin or on clothing.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

When handling concentrate wear protective eyewear (goggles or face shield) and rubber gloves. Applicators and handlers must wear coveralls over long-sleeved shirt, long pants, and chemical resistant footwear plus socks. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water.

USER SAFETY RECOMMENDATIONS

Users should wash hands thoroughly with soap and water before eating, drinking, chewing gum, using tobacco or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

FOR TERRESTRIAL USES. Keep out of lakes, ponds and streams. This pesticide is toxic to birds and fish. Do not apply directly to water, or to areas where surface water is present or to inter-tidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of wash waters.

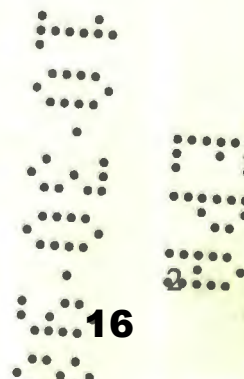
This product is highly toxic to bees and other beneficial insects exposed to direct contact on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area. Do not apply this product or allow it to drift to crops where beneficials are part of an Integrated Pest Management strategy.

PHYSICAL AND CHEMICAL HAZARDS

Strong oxidizing agent. **Corrosive.** Do not use in concentrated form. Mix only with water in accordance with label instructions. Never bring concentrate in contact with other pesticides, cleaners or oxidative agents.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.



AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about Personal Protective Equipment (PPE) and Restricted-Entry Interval (REI). The requirements in this box only apply to the uses of this product that are covered by the Worker Protection Standard.

There is a restricted entry of zero (0) hours for this product.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Store in original containers in a cool, well-vented area, away from direct sunlight. Do not allow product to become overheated in storage. This may cause increased degradation of the product, which will decrease product effectiveness. In case of spill, flood area with large quantities of water. Do not store in a manner where cross-contamination with other pesticides or fertilizers could occur.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Open dumping is prohibited. If wastes cannot be disposed of according to label directions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinses (or equivalent). Then offer for recycling or dispose in a sanitary landfill, or incineration, if allowed by state and local authorities by burning, stay out of smoke.

DIRECTIONS FOR USE:

- * Oxidate™ works best when diluted with water containing low levels of organic or inorganic materials, and with water having a neutral pH. Thoroughly rinse out tank with water before mixing concentrate. Oxidate™ will readily mix with clean, neutral water and does not require agitation.
- * Oxidate™ should not be combined or mixed with any other pesticide or fertilizer.
- * Oxidate™ is formulated with a minimal amount of surfactant for plants having waxy or hairy surfaces. Additional surfactant may be added, if needed.

Oxidate™ works by surface contact with the plants and materials being treated. It is important to ensure that all surfaces are thoroughly wetted. Oxidate™ does not produce any visible residue, distinct odor or deleterious effects to plants when used in accordance with label directions. Do not use at higher than recommended dilution rates as leaf burn may result.

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Do not apply this product through any irrigation system unless directed by the label; refer to Chemigation Directions for Use.

Use Rates and Directions:

Pre-Plant Dip Treatment -

Use Oxidate™ for the control of damping-off, root disease and stem rot disease caused by *Pythium*, *Phytophthora*, *Rhizoctonia*, *Fusarium* or *Thielaviopsis*, on seeds, seedlings, bulbs, or cuttings.

- 1) Mix 64-fl. oz. per 50 gallons of water.
- 2) Immerse plants or cuttings; remove and allow to drain. Do not rinse.

Soil Drench -

Oxidate™ is effective for the control of soil borne plant diseases such as *Pythium*, *Phytophthora*, *Rhizoctonia*, *Thielaviopsis* or *Fusarium*. Use as a soil drench at the time of seeding or transplanting, as well as a periodic drench throughout the plant's life. Oxidate™ can also be used on potting soil and growing mediums prior to planting.

- 1) Mix $\frac{1}{2}$ fl. oz. Oxidate™ per gallon of clean water.
- 2) Apply to soil or growing media to the point of saturation.
- 3) Wait fifteen minutes before planting or watering.

Foliar Spray Treatments for field grown crops, crops grown in commercial greenhouses or crops grown in other similar sites -

Oxidate™ works immediately on contact with any plant surface for control. Good coverage and wetting of the foliage is necessary.

Crops	Disease	Dilution Rate	Application Rate	Directions
Beans	Anthracnose Downy Mildew Powdery Mildew Rust	1:100	128 oz. ZeroTol per 100 gallons of water; apply 50-100 gallons of spray solution per acre.	Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
		1:100 - 1:300	40-128 oz. ZeroTol per 100 gallons of water; apply 50-100 gallons of spray solution per acre.	Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5-day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5-day interval spray cycle until harvest.
Broccoli Cauliflower Cabbage	Alternaria Leaf Spot Downy Mildew Powdery Mildew	1:100	128 oz. ZeroTol per 100 gallons of water; apply 50-100 gallons of spray solution per acre.	Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
		1:100 - 1:300	40-128 oz. ZeroTol per 100 gallons of water; apply 50-100 gallons of spray solution per acre.	Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5-day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5-day interval spray cycle until harvest.

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Crops	Disease	Dilution Rate	Application Rate	Directions
Citrus	Rust Scab Powdery Mildew Brown Rot Phytophthora	1:100	128 oz. Oxidate per 100 gallons of water; apply 50–100 gallons of spray solution per acre.	Pre-Bloom: Begin applications at ¼ - ½ inch green tip and continue on a five to seven day schedule through bloom.
		1:100 – 1:300	40–128 oz. Oxidate per 100 gallons of water; apply 50–100 gallons of spray solution per acre.	Curative: Spray diseased trees using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals. Preventive: Spray once a week until harvest.
Cucurbits	Alternaria Anthracnose Downy Mildew Powdery Mildew Pythium Rot	1:100	128 oz. Oxidate per 100 gallons of water; apply 50–100 gallons of spray solution per acre.	Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
		1:100 – 1:300	40–128 oz. Oxidate per 100 gallons of water; apply 50–100 gallons of spray solution per acre.	Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5-day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5-day interval spray cycle until harvest.
Onions	Botrytis Downy Mildew Powdery Mildew	1:100	128 oz. Oxidate per 100 gallons of water; apply 50–100 gallons of spray solution per acre.	Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
		1:100 – 1:300	40–128 oz. Oxidate per 100 gallons of water; apply 50–100 gallons of spray solution per acre.	Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5-day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5-day interval spray cycle until harvest.
Peppers	Anthracnose Phytophthora Blight Powdery Mildew	1:100	128 oz. Oxidate per 100 gallons of water; apply 50–100 gallons of spray solution per acre.	Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
		1:100 – 1:300	40–128 oz. Oxidate per 100 gallons of water; apply 50–100 gallons of spray solution per acre.	Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5-day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5-day interval spray cycle until harvest.
Potatoes	Early Blight Late Blight	1:100	128 oz. Oxidate per 100 gallons of water; apply 50–100 gallons of spray solution per acre.	Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.
		1:100 – 1:300	40–128 oz. Oxidate per 100 gallons of water; apply 50–100 gallons of spray solution per acre.	Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5-day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5-day interval spray cycle until harvest.

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Crops	Disease	Dilution Rate	Application Rate	Directions
Seed Potatoes	Fusarium	1: 50	2.5 oz. Oxidate per gallon of water.	Dip whole or cut tubers into tank of working solution. Let soak for a period of five minutes before removing seed pieces.
Tomatoes	Anthracnose Cladosporium Mold Early Blight Late Blight Powdery Mildew	1:100 1:100 - 1:300	128 oz. Oxidate per 100 gallons of water; apply 50-100 gallons of spray solution per acre. 40-128 oz. Oxidate per 100 gallons of water; apply 50-100 gallons of spray solution per acre.	Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals. Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5-day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5-day interval spray cycle until harvest.
Apples	Rusts Scab Powdery Mildew	1:100 1: 100	128 oz. Oxidate per 100 gallons of water; apply 50-100 gallons of spray solution per acre.	Curative: Spray diseased trees using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals. Pre-Bloom: Begin applications at ¼ - ½ inch green tip and continue on a five to seven day schedule through bloom.
Filberts	Eastern Filbert Blight Bacterial Blight	1:100 1: 100	128 oz. Oxidate per 100 gallons of water; apply 50-100 gallons of spray solution per acre.	Curative: Spray diseased trees using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals. Pre-Bloom: Begin applications at ¼ - ½ inch green tip and continue on a five to seven day schedule through bloom.
Bananas	Sigatoka	1:100 1:100 - 1:300	128 oz. Oxidate per 100 gallons of water; apply 50-100 gallons of spray solution per acre. 40-128 oz. Oxidate per 100 gallons of water; apply 50-100 gallons of spray solution per acre.	Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals. Preventive: Begin when plants are small. Apply first three treatments at 1:100, for 5-day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5-day interval spray cycle until harvest.
Grapes	Black Rot Downy Mildew Powdery Mildew	1:100 1:100 - 1:300	128 oz. Oxidate per 100 gallons of water; apply 50-100 gallons of spray solution per acre. 40-128 oz. Oxidate per 100 gallons of water; apply 50-100 gallons of spray solution per acre.	Curative: Spray diseased plants using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals. Preventive: Begin when shoots are small. Apply first three treatments at 1:100, for 5-day intervals. Reduce rate to 1:300 after the completion of third treatment and maintain 5-day interval spray cycle until harvest.

Crops	Disease	Dilution Rate	Application Rate	Directions
Stone Fruits Peaches Plums Cherries Nectarines Prunes	Downy Mildew Powdery Mildew Brown Rot	1:100	128 oz. Oxidate per 100 gallons of water; apply 50-100 gallons of spray solution per acre.	Pre-Bloom: Begin applications at ¼ - ½ inch green tip and continue on a five to seven day schedule through bloom. Curative: Spray diseased trees using a 1:100 rate for three consecutive days and continue treatments on five to seven day intervals.

Spray Treatments for newly harvested potatoes before storage –

Crops	Disease	Dilution Rate	Application Rate	Directions
Potatoes	Fusarium Tuber Rot Bacteria Soft Rot Silver Scurf	1: 50 – 1: 100	2.5 – 1.25 oz. Oxidate per gallon of water.	Spray diluted solution on tuber to runoff to achieve full and even coverage. Additional surfactant can be added as needed to aid in sticking. Use 1 to 2 gallons of water per ton of potatoes.

Direct injection into humidification water for postharvest potatoes in storage –

Crops	Disease	Dilution Rate	Application Rate	Directions
Potatoes	Fusarium Tuber Rot Bacteria Soft Rot Silver Scurf	1:100 – 1:300	2.25 – 1.5 oz. Oxidate per gallon of water.	Inject concentrate into makeup water used in humidification of postharvest potatoes in storage.

Chemigation Directions for Use

General Requirements:

- 1) Apply this product only through a sprinkler including a center pivot, lateral move, end tow, side wheel roll, traveler, solid set, hand move, flood basin or drip trickle irrigation system. Do not apply this product through any other type of irrigation system.
- 2) Crop injury or lack of effectiveness can result from non-uniform distribution of treated water.
- 3) Ensure that the irrigation system used is properly calibrated and if you have questions, call the state extension service or the equipment manufacturer.
- 4) Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless proper safety devices for public water systems are in place. Read label for instructions.
- 5) A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make any necessary adjustments should the need arise.

Specific Requirements:

- 1) Public water supply means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of 25 individuals daily at least 60 days throughout the year.
- 2) Chemigation systems connected to the public water systems must contain a functional, reduced-pressure zone (RPZ), backflow preventer or the functional equivalent in the water supply upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top of the overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.
- 3) The pesticide injection pipeline must contain a functional, automatic, quick closing check valve to prevent the flow of liquid back towards the injector.
- 4) The pesticide injection pipeline must contain a functional, normally closed, solenoid, operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being drawn from the supply tank when the irrigation system is either automatically or manually shut down.
- 5) The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.
- 6) Systems must use a metering pump, such as a positive displacement injection pump, or equivalent, effectively designed and constructed of materials that are compatible with pesticides and capable of being filled with a system interlock.
- 7) Do not apply when wind speed favors drift beyond the area intended for treatment.

Application Instructions:

- 1) Remove scale, pesticide residues, and other foreign matter from the chemical supply tank and entire injector system. Flush with clean water. Failure to provide a clean tank, void of scale or residues may cause product to lose effectiveness or strength.
- 2) Determine the treatment rates as indicated in the directions for use and make proper dilutions.
- 3) Prepare a solution in the chemical tank by filling the tank with the required water and then adding product as required. The product will immediately go into suspension without any required agitation.
- 4) Oxidate should not be applied in conjunction with any other pesticides or fertilizers; this may cause reduced performance of the product and should be avoided.

WARRANTY

This material conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing, method of application, weather, watering practices, nature of soil, potting medium, disease problem, condition of crop, incompatibility with other chemicals, pre-existing conditions and other conditions influencing the use of this product are beyond the control of the seller. Buyer assumes all risks associated with the use, storage, or handling of this material not in strict accordance with directions given herewith. NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY IS MADE.

Oxidate Broad Spectrum Bactericide/Fungicide
Last revised January 28, 1999

Anne Ball
7511C

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John A. Richards, Director
Federal Register Staff

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300872; FRL-6083-9]

RIN 2070-AB78

Hydrogen Peroxide; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the biochemical hydrogen peroxide on all food commodities when applied/used as an algaecide, fungicide, and bactericide at the rate of $\leq 1\%$ hydrogen peroxide per application on growing crops (all food commodities) and postharvest potatoes. Biosafe Systems submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996 requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of hydrogen peroxide.

DATES: This regulation is effective [*insert date of publication in the Federal Register*]. Objections and requests for hearings must be received by EPA on or before [*insert date 60 days after date of publication in the Federal Register*].

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP-300872], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300872], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP-300872]. No Confidential Business Information (CBI) should be

submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Anne Ball, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: 9th fl., Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703-308-8717; e-mail address: ball.anne@epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 23, 1998 (63 FR 50901) (FRL-6028-4), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) announcing the filing of a pesticide tolerance petition by Biosafe Systems, at that date at 45 E. Woodthrush Trail, East Medford, NJ 08055, at present at 80 Commerce St., Glastonbury, CT 06033. The notice included a summary of the petition prepared by the petitioner Biosafe Systems, the registrant. There were no comments received in response to the notice of filing. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of hydrogen peroxide. By this final rule, EPA is granting the petition. EPA is amending the existing exemption for hydrogen peroxide in accordance with the petition. Based on this action, EPA considers the existing exemption to be reassessed.

I. Risk Assessment and Statutory Findings

New section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(c)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...." Additionally, section 408(b)(2)(D) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

II. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Hydrogen peroxide at a concentration of 27.17% has a pH of 1.05 at which concentration EPA assumes a toxicity category I for skin and eye irritation. Biosafe has submitted toxicology information from open literature for aqueous solutions containing 6% hydrogen peroxide and for aqueous solutions containing 50% hydrogen peroxide. The concentrate (27.17% hydrogen peroxide) will be diluted with water at the rate of 1:50 or 1:100 or 1:300 and thus, the concentration of hydrogen peroxide in the product at the time of application will range from 0.09% to 0.54%. The information from open literature demonstrated that solutions containing 6% hydrogen peroxide have an acute oral $LD_{50} \geq 5,000$ milligram/kilogram (mg/kg) in rats (toxicity category III), an acute dermal $LD_{50} \geq 10,000$ mg/kg in rabbits (toxicity category IV), and an inhalation LC_{50} of 4 milligram/liter (mg/l) (toxicity category IV). The 6% hydrogen peroxide solutions are mild irritants to rabbit skin and cause severe irreversible corneal injury in half of the exposed rabbits (toxicity category I). Toxicology information from open literature demonstrated that solutions which contained 50% hydrogen peroxide have an acute oral $LD_{50} \leq 500$ mg/kg in rats (toxicity category II), and an acute dermal $LD_{50} \leq 1,000$ mg/kg in rabbits (toxicity category II). No deaths resulted after an 8-hour exposure of rats to saturated vapors of 90% hydrogen peroxide, $LC_{50} = 4$ mg/l (2,000 ppm). Solutions which contain 50% hydrogen peroxide also are extremely irritating (corrosive) to rabbit eyes (toxicity category I).

EPA has concluded that for food use at an application rate of $\leq 1\%$ hydrogen peroxide no apparent acute toxicity and subchronic toxicity end points exist to suggest a significant toxicity. An RfD (chronic toxicity) for hydrogen peroxide has not been estimated because of its short half-life in the environment and lack of any residues of toxicological concern. For similar reasons, an additional safety factor was not judged necessary to protect the safety of infants and children. Additionally, hydrogen peroxide is listed by the Food and Drug Administration as Generally Recognized As Safe (GRAS). Additionally hydrogen peroxide is used to treat food at a maximum level of 0.05% in milk used in cheesemaking, 0.04% in whey, 0.15% in starch and corn syrup, and 1.25% in emulsifiers containing fatty acid esters as bleaching agents (21 CFR 184.1366). As a GRAS substance hydrogen peroxide may be used in washing or to assist in the lye peeling of fruits and vegetables (21 CFR 173.315).

III. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

1. *Food.* For the proposed uses the concentrate of hydrogen peroxide will be diluted with water at the rate of 1:50, 1:100 or 1:300 corresponding to a low concentration of hydrogen peroxide in the product at the time of application (0.09–0.54%). The solution, having a low concentration of hydrogen peroxide, reacts on contact with the surface on which it is sprayed and degrades rapidly to oxygen and water. Therefore residues in or on treated food commodities of the algaecide/fungicide/bactericide hydrogen peroxide are expected to be negligible. Additional sources of the GRAS substance hydrogen peroxide in concentrations range from 0.04% to 1.25% in various foods as cited above (21 CFR 184.1366).

2. *Drinking water exposure.* At the proposed application rates, the use of hydrogen peroxide as an algaecide, fungicide, and bactericide to treat food commodities could result in a minimal transfer of residues to potential drinking water sources. This is due to the low application rate and the rapid chemical degradation of hydrogen peroxide into oxygen and water neither of which is of toxicological concern.

B. Other Non-Occupational Exposure

There may be minimal amounts of non-dietary exposure to hydrogen peroxide in homes through the infrequent and short topical use of the substance in treating minor skin injuries and in its use in oral mouthwashes. Exposure is expected to be minimal also because of the rapid chemical degradation of hydrogen peroxide into oxygen and water.

IV. Cumulative Effects

Because of the low use rates of hydrogen peroxide, its low toxicity and rapid degradation, EPA does not believe that there is any concern regarding the potential for cumulative effects of hydrogen peroxide with other substances due to a common mechanism of action. Because hydrogen peroxide is not known to have a common toxic metabolite with other substances, EPA has not assumed that hydrogen peroxide has a common mechanism of toxicity with other substances.

V. Determination of Safety for U.S. Population, Infants and Children

Because hydrogen peroxide is of low toxicity, the proposed uses employ low concentrations of hydrogen peroxide, and hydrogen peroxide degrades rapidly following application, EPA concludes that this exemption from the requirement of a tolerance in or on all food commodities for hydrogen peroxide when applied at $\leq 1\%$ will not pose a dietary risk under reasonably foreseeable circumstances. Further, the EPA Office of Water has stated that it has seen no new data that contradict the assessment previously given, which is that low concentrations of hydrogen peroxide do not typically persist in drinking water at levels that pose a health risk. Accordingly, EPA concludes that there is a reasonable certainty of no harm to consumers, including infants and children, from aggregate exposure to hydrogen peroxide.

VI. Other Considerations

A. Endocrine Disruptors

There is no evidence to suggest that hydrogen peroxide in the proposed concentrations will adversely affect the endocrine system.

B. Analytical Method(s)

An analytical method for the detection of residues of hydrogen peroxide is not applicable to this tolerance exemption because of the low concentration of hydrogen peroxide in the product at the time of application at the time of application ($\leq 1\%$) and its rapid degradation to water and oxygen on contact with crops.

C. Codex Maximum Residue Level

There are no Codex Maximum Residue Levels (MRLs) established for residues of hydrogen peroxide.

VII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) and as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which governs the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

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If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VIII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP-300872] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

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IX. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory*

Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

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Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments "to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates."

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct

compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

X. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure,
Agricultural commodities, Pesticides and pests, Reporting and recordkeeping
requirements.

Dated: June 3, 1999

Kathleen D. Knox

Kathleen D. Knox, Acting
Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Sandra Artis
Certified to be a true
copy of the original

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.1197 is revised to read as follows:

§180.1197 Hydrogen peroxide; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of hydrogen peroxide in or on all food commodities at the rate of $\leq 1\%$ hydrogen peroxide per application on growing crops and postharvest potatoes when applied as an algaecide, fungicide and bactericide.

[FR Doc. 99-????? Filed ??-??-99; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300872; FRL-6083-9]

RIN 2070-AB78

Hydrogen Peroxide; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the biochemical hydrogen peroxide on all food commodities when applied/used as an algacide, fungicide, and bactericide at the rate of $\leq 1\%$ hydrogen peroxide per application on growing crops (all food commodities) and postharvest potatoes. Biosafe Systems submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996 requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of hydrogen peroxide.

DATES: This regulation is effective [insert date of publication in the **Federal Register**]. Objections and requests for hearings must be received by EPA on or before [insert date 60 days after date of publication in the **Federal Register**].

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP-300872], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300872], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

99P-966

CONCURRENCES							
SYMBOL	7104	7104	7511c	7511c			
SURNAME	Artis	Artis	Ruby	KNOX			
DATE	6/2/99	6/2/99	6/3/99	6/3/99			

EPA Form 1320-1 (12-70)

OFFICIAL FILE COPY

Corrections:
→ p. 4: line 7: remove "o" from bactericide
→ p. 10: line 5: change "3" to "2"

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300872; FRL-6083-9]

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submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Anne Ball, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: 9th fl., Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703-308-8717; e-mail address: ball.anne@epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 23, 1998 (63 FR 50901) (FRL-6028-4), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) announcing the filing of a pesticide tolerance petition by Biosafe Systems, at that date at 45 E. Woodthrush Trail, East Medford, NJ 08055, at present at 80 Commerce St., Glastonbury, CT 06033. The notice included a summary of the petition prepared by the petitioner Biosafe Systems, the registrant. There were no comments received in response to the notice of filing. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of hydrogen peroxide. By this final rule, EPA is granting the petition. EPA is amending the existing exemption for hydrogen peroxide in accordance with the petition. Based on this action, EPA considers the existing exemption to be reassessed.

I. Risk Assessment and Statutory Findings

New section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(c)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...." Additionally, section 408(b)(2)(D) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

II. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Hydrogen peroxide at a concentration of 27.17% has a pH of 1.05 at which concentration EPA assumes a toxicity category I for skin and eye irritation. Biosafe has submitted toxicology information from open literature for aqueous solutions containing 6% hydrogen peroxide and for aqueous solutions containing 50% hydrogen peroxide. The concentrate (27.17% hydrogen peroxide) will be diluted with water at the rate of 1:50 or 1:100 or 1:300 and thus, the concentration of hydrogen peroxide in the product at the time of application will range from 0.09% to 0.54%. The information from open literature demonstrated that solutions containing 6% hydrogen peroxide have an acute oral $LD_{50} \geq 5,000$ milligram/kilogram (mg/kg) in rats (toxicity category III), an acute dermal $LD_{50} \geq 10,000$ mg/kg in rabbits (toxicity category IV), and an inhalation LC_{50} of 4 milligram/liter (mg/l) (toxicity category IV). The 6% hydrogen peroxide solutions are mild irritants to rabbit skin and cause severe irreversible corneal injury in half of the exposed rabbits (toxicity category I). Toxicology information from open literature demonstrated that solutions which contained 50% hydrogen peroxide have an acute oral $LD_{50} \leq 500$ mg/kg in rats (toxicity category II), and an acute dermal $LD_{50} \leq 1,000$ mg/kg in rabbits (toxicity category II). No deaths resulted after an 8-hour exposure of rats to saturated vapors of 90% hydrogen peroxide, $LC_{50} = 4$ mg/l (2,000 ppm). Solutions which contain 50% hydrogen peroxide also are extremely irritating (corrosive) to rabbit eyes (toxicity category I).

EPA has concluded that for food use at an application rate of $\leq 1\%$ hydrogen peroxide no apparent acute toxicity and subchronic toxicity end points exist to suggest a significant toxicity. An RfD (chronic toxicity) for hydrogen peroxide has not been estimated because of its short half-life in the environment and lack of any residues of toxicological concern. For similar reasons, an additional safety factor was not judged necessary to protect the safety of infants and children. Additionally, hydrogen peroxide is listed by the Food and Drug Administration as Generally Recognized As Safe (GRAS). Additionally hydrogen peroxide is used to treat food at a maximum level of 0.05% in milk used in cheesemaking, 0.04% in whey, 0.15% in starch and corn syrup, and 1.25% in emulsifiers containing fatty acid esters as bleaching agents (21 CFR 184.1366). As a GRAS substance hydrogen peroxide may be used in washing or to assist in the lye peeling of fruits and vegetables (21 CFR 173.315).

III. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

1. *Food.* For the proposed uses the concentrate of hydrogen peroxide will be diluted with water at the rate of 1:50, 1:100 or 1:300 corresponding to a low concentration of hydrogen peroxide in the product at the time of application (0.09–0.54%). The solution, having a low concentration of hydrogen peroxide, reacts on contact with the surface on which it is sprayed and degrades rapidly to oxygen and water. Therefore residues in or on treated food commodities of the algaecide/fungicide/bactericide hydrogen peroxide are expected to be negligible. Additional sources of the GRAS substance hydrogen peroxide in concentrations range from 0.04% to 1.25% in various foods as cited above (21 CFR 184.1366).

2. *Drinking water exposure.* At the proposed application rates, the use of hydrogen peroxide as an algaecide, fungicide, and bactericide to treat food commodities could result in a minimal transfer of residues to potential drinking water sources. This is due to the low application rate and the rapid chemical degradation of hydrogen peroxide into oxygen and water neither of which is of toxicological concern.

B. Other Non-Occupational Exposure

There may be minimal amounts of non-dietary exposure to hydrogen peroxide in homes through the infrequent and short topical use of the substance in treating minor skin injuries and in its use in oral mouthwashes. Exposure is expected to be minimal also because of the rapid chemical degradation of hydrogen peroxide into oxygen and water.

IV. Cumulative Effects

Because of the low use rates of hydrogen peroxide, its low toxicity and rapid degradation, EPA does not believe that there is any concern regarding the potential for cumulative effects of hydrogen peroxide with other substances due to a common mechanism of action. Because hydrogen peroxide is not known to have a common toxic metabolite with other substances, EPA has not assumed that hydrogen peroxide has a common mechanism of toxicity with other substances.

V. Determination of Safety for U.S. Population, Infants and Children

Because hydrogen peroxide is of low toxicity, the proposed uses employ low concentrations of hydrogen peroxide, and hydrogen peroxide degrades rapidly following application, EPA concludes that this exemption from the requirement of a tolerance in or on all food commodities for hydrogen peroxide when applied at $\leq 1\%$ will not pose a dietary risk under reasonably foreseeable circumstances. Further, the EPA Office of Water has stated that it has seen no new data that contradict the assessment previously given, which is that low concentrations of hydrogen peroxide do not typically persist in drinking water at levels that pose a health risk. Accordingly, EPA concludes that there is a reasonable certainty of no harm to consumers, including infants and children, from aggregate exposure to hydrogen peroxide.

VI. Other Considerations

A. Endocrine Disruptors

There is no evidence to suggest that hydrogen peroxide in the proposed concentrations will adversely affect the endocrine system.

B. Analytical Method(s)

An analytical method for the detection of residues of hydrogen peroxide is not applicable to this tolerance exemption because of the low concentration of hydrogen peroxide in the product at the time of application at the time of application ($\leq 1\%$) and its rapid degradation to water and oxygen on contact with crops.

C. Codex Maximum Residue Level

There are no Codex Maximum Residue Levels (MRLs) established for residues of hydrogen peroxide.

VII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) and as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which governs the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

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In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

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Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

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Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

X. Submission to Congress and the Comptroller General

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Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 3, 1999.

Kathleen D. Knox,

Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180-[AMENDED]

1. The authority citation for part 180 continues to read as follows:

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~~2.~~ Section 180.1197 is revised to read as follows:

§180.1197 Hydrogen peroxide; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of hydrogen peroxide in or on all food commodities at the rate of $\leq 1\%$ hydrogen peroxide per application on growing crops and postharvest potatoes when applied as an algaecide, fungicide and bactericide.


[FR Doc. 99-????? Filed ??-??-99; 8:45 am]

BILLING CODE 6560-50-F

H₂O₂; 180.11.97 exemption



Anne Ball
06/23/99 04:09 PM

To: aroberts@tsgusa.com
cc:
Subject: Re: Oxidate approval 

You are most welcome and thank you for those kind words. It has always been a pleasure working with you.

aroberts@tsgusa.com on 06/23/99 02:18:25 PM



aroberts@tsgusa.com on 06/23/99 02:18:25 PM

To: Anne Ball/DC/USEPA/US@EPA
cc:
Subject: Oxidate approval

Anne - Thank you for faxing the Reg Not for Oxidate. And a big thank you for being so responsive and helpful throughout this registration. I am so glad to have this one done! Thanks again and all the best, Amy Roberts



- att1.htm



Anne Ball
05/21/99 09:53 AM

To: rob@biosafesystems.com
cc:
Subject: Re: OXIDATE 

Have been trying my best. The hold up was the final rule -exemption of tolerance reassessment draft (to cover all the uses for Oxidate) which was finally OK'd by OGC after which I sent it electronically to the Fed Register Office for their typesetting, etc--then it gets returned here for the director's signature, after which it is returned to the FR office and published in the FR. When published I can get the Registration Notice signed here by the director and mail and fax it to you. Believe me I have had the registration notice ready for signature for some time now.
rob@biosafesystems.com on 05/20/99 01:56:05 PM



rob@biosafesystems.com on 05/20/99 01:56:05 PM

Please respond to rob@biosafesystems.com

To: Anne Ball/DC/USEPA/US@EPA
cc:
Subject: OXIDATE

The pressure is mounting. The planting season has come and gone in most parts of the country. Can you please beg those people to sign that registration and to send it along by fax. I know you told my wife that it will most likely be next week and you didn't know exactly what day it would be. the only thing that I'm trying to request is that we not let this slip into the week after next week.

Thanks , Rob



rob@biosafesystems.com on 05/20/99 01:56:05 PM

Please respond to rob@biosafesystems.com

To: Anne Ball/DC/USEPA/US@EPA

cc:

Subject: OXIDATE

The pressure is mounting. The planting season has come and gone in most parts of the country. Can you please beg those people to sign that registration and to send it along by fax. I know you told my wife that it will most likely be next week and you didn't know exactly what day it would be. the only thing that I'm trying to request is that we not let this slip into the week after next week.

Thanks , Rob



aroberts@tsgusa.com on 04/02/99 08:59:51 AM

To: ball.anne
cc:
Subject: Oxidate

Hi Anne - I saw the posting for Oxidate in this past Wednesday's FR. While the 30-day clock is ticking let me know if there is anything I can do, as far as any label or other revisions. I think you had said we are all set, and you are just waiting on finalization of the FR exemption listing from OGC. I will be out of the office April 9 through April 19, but will check with you after the 19th to see if we need to do any final revisions. Have a great Easter weekend! All the best, Amy Roberts



- att1.htm

Anne Ball
01/12/99 09:00 AM

To: rob@biosafesystems.com
cc: aroberts@tsgusa.com
Subject: Re: Oxidate registration

Rob--About the inerts: So far two of the inerts have at this point not been cleared for food use. The [REDACTED] produced surfactant is cleared for food use (once [REDACTED] had sent us the composition in accordance with Amy's earlier request). The two in question are at present writing being researched in the Agency. The statutory reference is 40 CFR 180.1001 (c). This lists the materials ...exempted from the requirement of a tolerance when used ...as an inert ingredient in pesticide formulations..... ..[for food use]. I will be back with Amy hopefully this week about the outcome and how best to proceed in the interest of time.

biosafesystems@biosafesystems.com on 01/11/99 05:13:13 PM



biosafesystems@biosafesystems.com on 01/11/99 05:13:13 PM

Please respond to rob@biosafesystems.com

To: Ball.Anne
cc:
Subject: Re: Oxidate registration

Anne: Thanks for getting back to me. I just talked with Amy and she said that all the inert ingredients have been submitted and approved. She said there was a delay in getting the information from [REDACTED], but that information was submitted on Dec 17, 1998.

Ball.Anne@epamail.epa.gov wrote:

> Rob--The Federal Register Final Rule needs to be published and three inert
> ingredient ingredients need to be cleared for food use. I am working on both
> these steps. Best regards

>

> biosafesystems@biosafesystems.com on 01/08/99 04:16:34 PM

>

> Please respond to rob@biosafesystems.com

>

> To: Ball.Anne

> cc:

> Subject: Oxidate registration

>

> Anne: I just wanted to touch base with you to get some idea as to our

> status on the Oxidate registration. Amy was not too clear as to our

> exact status. She seemed to think that we are waiting on Federal

> Register notice. Could you please either call or e-mail me back with an

> update,

>

> Thank you


>


> Rob

>

> --

-
MZ + /8EAAg-

 Anne Ball
01/11/99 08:21 AM

To: rob@biosafesystems.com
cc:
Subject: Re: Oxidate registration 

Rob--The Federal Register Final Rule needs to be published and three inert ingredient ingredients need to be cleared for food use. I am working on both these steps. Best regards
biosafesystems@biosafesystems.com on 01/08/99 04:16:34 PM



biosafesystems@biosafesystems.com on 01/08/99 04:16:34 PM

Please respond to rob@biosafesystems.com


To: Ball.Anne
cc:
Subject: Oxidate registration


Anne: I just wanted to touch base with you to get some idea as to our status on the Oxidate registration. Amy was not too clear as to our exact status. She seemed to think that we are waiting on Federal Register notice. Could you please either call or e-mail me back with an update,

Thank you

Rob

--


 Anne Ball
04/20/99 02:20 PM

To: John Streeter/DC/USEPA/US@EPA
cc: Roy Sjoblad/DC/USEPA/US@EPA
Subject: Re: Please change action codes in PRAT 

John--Thank you very much.
04/20/99 01:07 PM

John Streeter

04/20/99 01:07 PM


To: Anne Ball/DC/USEPA/US@EPA
cc: Roy Sjoblad/DC/USEPA/US@EPA
Subject: Re: Please change action codes in PRAT 

Anne,

These changes are completed.

Regards,

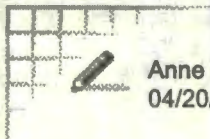
John.
Anne Ball

 Anne Ball
04/20/99 11:53 AM

To: John Streeter/DC/USEPA/US@EPA
cc: Roy Sjoblad/DC/USEPA/US@EPA
Subject: Please change action codes in PRAT

For File symbol 70299-E, product name: OXIDATE BROAD SPECTRUM BACTERICIDE/FUNGICIDE, the action code needs to be corrected from 180 to 188. This affects 5 submissions which need to have their respective action codes corrected as follows: 1) S547816 (from 180 to 188); 2) S551047 (from 181 to 189); 3) S554271 (from 181 to 189); 4) S556171 (from 181 to 189); and 5) S557264 (from 181 to 189).

I could not effect these changes in PRAT myself (at the case level) . BPPD has determined that this product is not a first food or feed use. There are some food uses for which there is an exemption from the requirement of a tolerance (by AD in May 1998). BPPD's present draft final rule for an exemption is as a reassessment of the May 1988 AD final rule.



Anne Ball

04/20/99 11:53 AM

To: John Streeter/DC/USEPA/US@EPA
cc: Roy Sjoblad/DC/USEPA/US@EPA
Subject: Please change action codes in PRAT

For File symbol 70299-E, product name: OXIDATE BROAD SPECTRUM BACTERICIDE/FUNGICIDE, the action code needs to be corrected from 180 to 188. This affects 5 submissions which need to have their respective action codes corrected as follows: 1) S547816 (from 180 to 188); 2) S551047 (from 181 to 189); 3) S554271 (from 181 to 189); 4) S556171 (from 181 to 189); and 5) S557264 (from 181 to 189).

I could not effect these changes in PRAT myself (at the case level) . BPPD has determined that this product is not a first food or feed use. There are some food uses for which there is an exemption from the requirement of a tolerance (by AD in May 1998). BPPD's present draft final rule for an exemption is as a reassessment of the May 1988 AD final rule.

envsubset
03/31/99 04:33 PM

Please respond to epa-pest2@valley.rtpnc.epa.gov

To: epa-pest2@valley.rtpnc.epa.gov

cc:

Subject: BioSafe Systems; Application to Register a Pesticide

[Federal Register: March 31, 1999 (Volume 64, Number 61)]

[Notices]

[Page 15363-15364]

> From the Federal Register Online via GPO Access [wais.access.gpo.gov]

[DOCID:fr31mr99-64]

ENVIRONMENTAL PROTECTION AGENCY

[OPP-30474; FRL-6070-9]

BioSafe Systems; Application to Register a Pesticide Product

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of an application to register the pesticide product Oxidate Broad Spectrum Bactericide/Fungicide, containing an active ingredient involving a changed pattern pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

DATES: Written comments must be submitted by April 30, 1999.

ADDRESSES: By mail, submit written comments identified by the document control number [OPP-30474] File Symbol (70299-E) to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow the instructions under ``SUPPLEMENTARY INFORMATION.'' No Confidential Business Information (CBI) should be submitted through e-mail.

Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as

CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. The public docket is available for public inspection in Rm. 119 at the Virginia address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Anne Ball, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location/telephone number and e-mail address: Rm. 910W44, CM #2, 1921 Jefferson Davis Hwy, Arlington, VA, 703-308-8717; e-mail: ball.anne@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA received an application from BioSafe Systems, 80 Commerce St., Glastonbury, CT 06033, to register the pesticide product Oxidate Broad Spectrum Bactericide/Fungicide (EPA File Symbol 70299-E), containing the active ingredient hydrogen peroxide (hydrogen dioxide) at 27%. This application involves a changed use pattern for the active ingredient pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. In addition to the currently registered uses, Oxidate will be used as a fungicide and bactericide on growing crops such as (beans, broccoli, cauliflower, cabbage, citrus, cucurbits, onions, peppers, potatoes, tomatoes, apples, filberts, bananas, grapes, stonefruits, and postharvest potatoes). Notice of receipt of this application does not imply a decision by the Agency on the application.

Notice of approval or denial of an application to register a pesticide product will be announced in the Federal Register. The procedure for requesting data will be given in the Federal Register if an application is approved.

Comments received within the specified time period will be considered before a final decision is made; comments received after the time specified will be considered only to the extent possible without delaying processing of the application.

Public Record and Electronic Submissions

The official record for this notice, as well as the public version, has been established for this notice under docket number [OPP-30474] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official notice record is located at the address in ``ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:
opp-docket@epamail.epa.gov

[[Page 15364]]

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket number [OPP-30474] Electronic comments on this notice may be filed online at many Federal Depository Libraries.

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection, Pesticides and pest, Product registration.

Dated: March 17, 1999.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 99-7914 Filed 3-30-99; 8:45 am]
BILLING CODE 6560-50-F

This document will publish in the
FEDERAL REGISTER of 3/31/99.
Approximately 24 hours after
publication, page numbers are
available by calling the Federal
Register Staff (FRS) at 202-260-2253.
Please refer to the FRL number at
the top of the first page or the
number at the bottom left corner of
the first page.

Copies of the actual FEDERAL REGISTER
publication are made available through
the FRS weekly distribution. Extra
copies may be made by the interested
party from a copy of the FEDERAL REGISTER
available in the FRS Office.
(NE Mail G-304).

John A. Richards, Director
Federal Register Staff

Anne Ball
7511C

ENVIRONMENTAL PROTECTION AGENCY

[OPP-30474; FRL-6070-9]

BioSafe Systems; Application to Register a Pesticide Product

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of an application to register the pesticide product Oxidate Broad Spectrum Bactericide/Fungicide, containing an active ingredient involving a changed pattern pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

DATES: Written comments must be submitted by (*insert date 30 days after date of publication in the Federal Register*).

ADDRESSES: By mail, submit written comments identified by the document control number [OPP-30474] File Symbol (70299-E) to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

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Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. The public docket is available for public inspection in Rm. 119 at the Virginia address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding holidays.

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SUPPLEMENTARY INFORMATION: EPA received an application from BioSafe Systems, 80 Commerce St., Glastonbury, CT 06033, to register the pesticide product Oxidate Broad Spectrum Bactericide/Fungicide (EPA File Symbol 70299-E), containing the active ingredient hydrogen peroxide (hydrogen dioxide) at 27%. This application involves a changed use pattern for the active ingredient

pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. In addition to the currently registered uses, Oxidate will be used as a fungicide and bactericide on growing crops such as (beans, broccoli, cauliflower, cabbage, citrus, cucurbits, onions, peppers, potatoes, tomatoes, apples, filberts, bananas, grapes, stonefruits, and postharvest potatoes). Notice of receipt of this application does not imply a decision by the Agency on the application.

Notice of approval or denial of an application to register a pesticide product will be announced in the **Federal Register**. The procedure for requesting data will be given in the **Federal Register** if an application is approved.

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Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket number [OPP-30474] Electronic comments on this notice may be filed online at many Federal Depository Libraries.

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection, Pesticides and pest, Product registration.

Dated: 3-17-99



Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 99-????? Filed ??-??-99; 8:45 am]

BILLING CODE 6560-50-F

Sandra Artis
CORRECTED BY 15 11 1999
COPY OF THE ORIGINAL

FEDERAL REGISTER DRAFT INFORMATION SHEET FOR PUBLICATION

1. Application, Register Pest. Prod. with New Active Ingredient
- ☒ 2. Application, Register Pest. Prod. entailing a changed Use Pattern
3. Approval, Application to Register Pest. Prod. with New Active Ingredient
4. Approval, Application to Register Pest. Prod. entailing a changed Use Pattern

PLEASE PROVIDE THE FOLLOWING INFORMATION

a. Company Name/Address:

Biosafe Systems
80 Commerce Street
Glastonbury, CT 06033

b. Product Name:

Oxidate Broad Spectrum Bactericide/Fungicide

c. Type of Product (Insecticide/Rodenticide, etc) Other:

Bactericide/Fungicide

d. File Symbol/Reg. No.:

70299-E

e. Chemical/Microbial Name:

Hydrogen Peroxide (Hydrogen dioxide; synonym)

f. % Active Ingredient:

27%

g. Proposed/Approved Classification:

h. Use Pattern: (For Changed Use Pattern Application, specify the change)

~~Food use Crops~~

~~Intentional control of plant diseases in field grown crops, greenhouses and storage~~

i. Type Registration/Approval of Registration: FULL

CONDITIONAL

j. Other information you think appropriate for publication purposes:

Note: Reregistration Eligibility Decision
on Peroxy Compounds
Published December 1993 (in Antimicrobial Division)
No factsheet except p1-4 of above document.
(Publication prior to requirement of Fact Sheet)

PROVIDE WITH THIS SHEET THE FOLLOWING INFORMATION

a. Legible copy of product label

b. List of Data References (FOR APPROVAL NOTICES)

MRID NOS.	443402 - 01	441160 - 02
	443142 - 01	441160 - 03
	441160 - 01	441160 - 04
		441160 - 05

Submitted by: ANNE BALL RM 910W44 3088117 BPPD

Forward to FRS, Rm. NEG009 Attn: Emily Glover 202-260-9110

7104

Received FRS by: _____ Date _____

GG: Return it to BPPD 3/5



WASHINGTON

1101 17th Street, N.W.
Suite 500
Washington, D.C. 20036
Telephone 202 223-4392
Fax 202 872-0745

Anne Ball
Biopesticide and Pollution Prevention Division
Office of Pesticide Programs
1921 Jefferson Davis Highway
Arlington, VA 22202

January 28, 1999

**RE: Oxidate Broad Spectrum Bactericide / Fungicide
EPA File Symbol 70299-E
Revised label**

SAN FRANCISCO

2700 Steuart Street Tower
One Market
San Francisco, CA 94105
Telephone 415 267-4119
Fax 415 267-4198

Dear Ms. Ball:

Per our telephone conversations, enclosed you will find a revised label for the above referenced product. The label has been revised to delete the last sentence of the Agricultural Use Requirements box, starting "PPE required for early entry...". Additionally, three new use sites have been added to the label, as follows:

Citrus
Newly harvested potatoes going into storage
Postharvest potatoes in storage

Should you have any questions or comments, please do not hesitate to let me know.

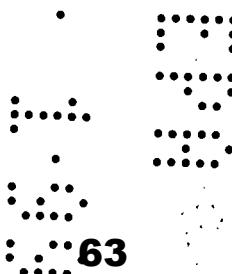
SACRAMENTO

712 Fifth Street
Suite A
Davis, CA 95616
Telephone 530 757-1298
Fax 530 757-1299

Sincerely,

Amy Plato Roberts
Regulatory Consultant for BioSafe Systems, Inc.

Direct dial (202) 828-8964



BPPD PRAT ACTION CODING FORM

PM 90: Janet Anderson

REVIEWER: DMR6300L

(ASSIGNED BY: SJ0370D)

EPA REG./FILE SYMBOL 76299-E

ACTION CODE 187 189

SUBMISSION BARCODE 5547816

Revised Label

Date on Application 1/28/99

EPA Received Date 2/1/99

PM Received Date 2/2/99

Assigned in PRAT YES _____ NO _____

Completed by: T. BETHA S. Diana Anderson Date 2/5/99

.....

FINAL ACTION

Response Code _____

Response Date: / /

MUS: _____ (1) Cite All

_____ (4) Not Applicable

_____ (8) Selective

CRP: Yes _____ No _____

Restricted Use: Yes _____ No _____

Manufacturing Use: Yes _____ No _____

Exclusive Use: Yes _____ No _____



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

259579

Application for Pesticide - Section I

1. Company/Product Number 70299-E	2. EPA Product Manager Anne Ball	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Oxide Broad Spectrum Bactericide / Fungicide	PM# 91 / BPPD	
5. Name and Address of Applicant (Include ZIP Code) BioSafe Systems 80 Commerce Street Glastonbury, CT 06033 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of a revised label for a pending registration application, per telephone conversation with Anne Ball (703) 308-8717.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> _____	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Amy Plato Roberts	Title Regulatory Consultant	Telephone No. (Include Area Code) (202) 828-8964	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received *(Stamped)*
2. Signature 	3. Title Regulatory Consultant		
4. Typed Name Amy Plato Roberts	5. Date January 28, 1999		

**CHEMICAL NAME/PESTICIDE CHEMICAL CODE (PCC)
REQUEST FORM**

CR#: 99-0009

REQUESTOR NAME: Anne Ball

TEL: (703) 308-8717

ORG.: BPPD / microbial

(DIV./BR.)

REQUEST DATE: 1/11/99

ROOM: 910

MAIL CODE: 7511C

CSF ATTACHED:

- ☒ YES If CSF is attached complete Item A and the chemical name in Item B
☐ NO If CSF is not attached complete Items A through C.

A. INFORMATION REQUIRED:

☒ Check Applicable Category

☒ Provide PCC and Tolerance Exemption Status For Food-Use Inert Ingredient(s)

☐ Provide PCC for Non-Food Use Inert Ingredient(s)

☐ Provide PCC for Active Ingredient(s)

☐ Provide PCC for Dye

☐ Determine if Fragrance is Acceptable for Use in Formulation

☐ Other (Describe): _____

B. INGREDIENT INFORMATION:

Ingredient No. 1:

Chem. Name: _____

Trade Name: _____

CAS Reg. No.: _____

Ingredient No. 2:

Chem. Name: _____

Trade Name: _____

CAS Reg. No.: _____

Ingredient No. 3:

Chem. Name: _____

Trade Name: _____

CAS Reg. No.: _____

Ingredient No. 4:

Chem. Name: _____

Trade Name: _____

CAS Reg. No.: _____

C. PESTICIDE PRODUCT INFORMATION:

EPA Reg. No./File Symbol: 70299-E Product Name: _____

Registrant: _____

Food-Use Pesticide: ☐ YES ☐ NO

Present in Formulation (For Fragrance/Dyes only): _____ %

INFORMATION REPORTED:

Ingredient No. 1:

PCC: _____

TOL. STATUS: 40 CFR 180.1001 (c), (d)

OTHER INF.: _____

Ingredient No. 2:

PCC: _____

TOL. STATUS: Not exempted for food use,

OTHER INF.: _____

Ingredient No. 3:

PCC: _____

TOL. STATUS: _____

OTHER INF.: _____

Ingredient No. 4:

PCC: _____

TOL. STATUS: _____

OTHER INF.: _____

Completed By: LINDA

Date Completed: 01/13/99

Once completed, this form may be entitled to treatment as CBI under section 10 of FIFRA, If so, a red CBI cover should be affixed to the request form and the document handled accordingly.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

259579

Application for Pesticide - Section I

1. Company/Product Number 70299-E	2. EPA Product Manager Anne Ball	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Oxidate Broad Spectrum Bactericide/Fungicide	PM# 91/ BPPD	
5. Name and Address of Applicant (Include ZIP Code) BioSafe Systems 80 Commerce Street Glastonbury, CT 06033 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of a revised Confidential Statement of Formula.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Amy Plato Roberts		Title Regulatory Consultant	
		Telephone No. (Include Area Code) (202) 828-8964	
<p align="center">Certification</p> <p>I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.</p>			
2. Signature 		3. Title Regulatory Consultant	
4. Typed Name Amy Plato Roberts		5. Date January 20, 1999	
6. Date Application Received (Stamped)			

BPP
JAN 8 1999



WASHINGTON

1101 17th Street, N.W.
Suite 500
Washington, D.C. 20036
Telephone 202 223-4392
Fax 202 872-0745

Anne Ball
Biopesticides and Pollution Prevention Division (7511C)
Office of Pesticide Programs, EPA
1921 Jefferson Davis Highway
Arlington, VA 22202

January 20, 1999

**RE: Oxidate™ Broad Spectrum Bactericide/Fungicide
EPA File Symbol 70299-E
Revised CSF**

SAN FRANCISCO

2700 Steuart Street Tower
One Market
San Francisco, CA 94105
Telephone 415 267-4119
Fax 415 267-4198

Dear Anne:

Per our discussions, enclosed you will find a revised Confidential Statement of Formula for Oxidate™ Broad Spectrum Bactericide/Fungicide. The Confidential Statement of Formula is revised to remove the inert ingredient that is not approved for use on food per 40 CFR 180.1001. Should you have any questions or comments, please do not hesitate to let me know.

Sincerely,

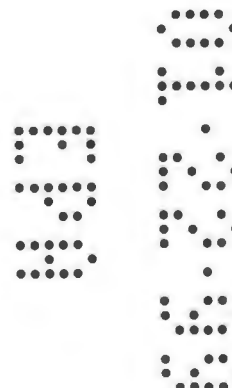
Amy Plato Roberts
Regulatory Consultant for BioSafe Systems

SACRAMENTO

712 Fifth Street
Suite A
Davis, CA 95616
Telephone 530 757-1298
Fax 530 757-1299

Direct dial (202) 828-8964

cc: Rob Larose, BioSafe Systems



COPY

Technology Sciences Group Inc.
1101 17th Street, N.W., Suite 500
Washington, D.C. 20036
Telephone: (202) 223-4392
Fax: (202) 872-0745
www.tsghusa.com



FACSIMILE TRANSMITTAL SUMMARY

Date: October 26, 1998
Addressee: [REDACTED]
Telephone: [REDACTED]
Fax: [REDACTED]
Number of Pages: two (2)
Sender: Amy Plato Roberts
Cc: Rob Larose, BioSafe Systems, (860) 657-3388

RE: Chemical composition information for [REDACTED]

[REDACTED]

Per my telephone message of today, I am requesting [REDACTED] forward information on the exact chemical composition of the above referenced product to the U.S. EPA, per their request. My client BioSafe Systems is utilizing [REDACTED] in a pesticide product that is intended for use on food. As the MSDS for [REDACTED], EPA is requiring information on the what the other <40% consists of. This information can be forwarded by you to EPA directly, as confidential business information. Chemical composition information should consist of **the chemical name, CAS Number and % by weight of each ingredient** in the product. Please forward the information to the following:

Anne Ball
Regulatory Action Leader
Biopesticides and Pollution Prevention Division (H7511C)
Office of Pesticide Programs, EPA
401 M Street, S.W.
Washington, D.C. 20460-0001



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

259579

Application for Pesticide - Section I

1. Company/Product Number 70299-E	2. EPA Product Manager Anne Ball 308-3717	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Oxamate Broad Spectrum Bactericide / Fungicide	PM# 91 / BPPD	
5. Name and Address of Applicant (Include ZIP Code) BioSafe Systems 80 Commerce St Glastonbury, CT 06033 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of MSDS for inert ingredients, per Anne Ball's request, and revised product label - refer to enclosed letter dated October 26, 1998.

Section - III

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Amy Plato Roberts		Title Regulatory Consultant	
		Telephone No. (Include Area Code) (202) 828-8964	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			
2. Signature 		3. Title Regulatory Consultant	
4. Typed Name Amy Plato Roberts		5. Date October 26, 1998	
6. Date Application Received (Stamped) 			



Inert ingredient information may be entitled to confidential treatment

WASHINGTON

1101 17th Street, N.W.
Suite 500
Washington, D.C. 20036
Telephone 202 223-4392
Fax 202 872-0745

Anne Ball
Regulatory Action Leader
Biopesticides and Pollution Prevention Division (7511C)
Office of Pesticide Programs, EPA
1921 Jefferson Davis Highway
Arlington, VA 22202

October 26, 1998

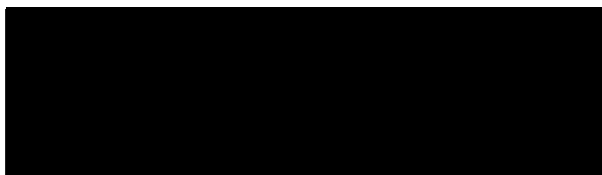
**RE: Oxidate™ Broad Spectrum Bactericide / Fungicide
EPA File Symbol 70299-E
Application for registration dated July 7, 1998**

SAN FRANCISCO

2700 Steuart Street Tower
One Market
San Francisco, CA 94105
Telephone 415 267-4119
Fax 415 267-4198

Dear Anne:

Per your request, enclosed you will find MSDSs for the inert ingredients in the above listed product, as follows:



SACRAMENTO

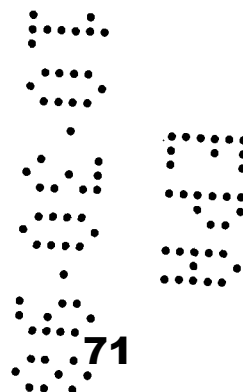
712 Fifth Street
Suite A
Davis, CA 95616
Telephone 530 757-1298
Fax 530 757-1299

As you will note, the chemical composition for all the inert ingredient products is 99% - 100% with the exception of the inert ingredient product [REDACTED]. As such, I have requested that the manufacturer of [REDACTED], forward to you, under a separate cover as confidential business information, the chemical composition of this product. To that end, enclosed you will also find a copy of correspondence to the manufacturer requesting this information. You should receive it shortly.

Also enclosed is an updated Confidential Statement of Formula (CSF); updated to show a new source of supply for the [REDACTED] (MSDS listed above corresponds with the new source of supply). No other changes have been made to the CSF.

E-mail tsg@tsgusa.com

<http://www.tsgusa.com>





WASHINGTON

1101 17th Street, N.W.

Suite 500

Washington, D.C. 20036

Telephone 202 223-4392

Fax 202 872-0745

Page 2

October 26, 1998

Lastly, enclosed you will find a revised product label for Oxidate™ Broad Spectrum Bactericide / Fungicide. We have revised the label to include expanded application rates and directions for use, based on the results of recent efficacy studies. In addition, I have corrected the active ingredient listing to read "Hydrogen dioxide," which is consistent with the already registered ZeroTol label. All changes are highlighted for reference.

Should you have any further questions or comments, please let me know.

SAN FRANCISCO

2700 Steuart Street Tower

One Market

San Francisco, CA 94105

Telephone 415 267-4119

Fax 415 267-4198

Sincerely,

Amy Plato Roberts

Regulatory Consultant for BioSafe Systems

Direct dial (202) 828-8964

cc: Rob Larose, BioSafe Systems

SACRAMENTO

712 Fifth Street

Suite A

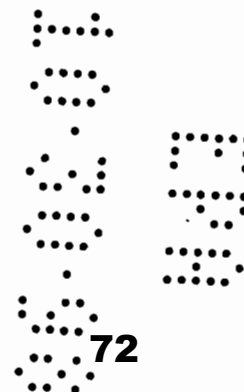
Davis, CA 95616

Telephone 530 757-1298

Fax 530 757-1299

E-mail tsg@tsgusa.com

<http://www.tsgusa.com>



BPPD PRAT ACTION CODING FORM

PM 90: Janet Anderson

REVIEWER: ANNIE BOZZ
(ASSIGNED BY: STOB200)

EPA REG./FILE SYMBOL 70299-E

ACTION CODE 181 189

SUBMISSION BARCODE 5554271

Date on Application 12-17-98

EPA Received Date 12-21-98

PM Received Date 12-24-98

Assigned in PRAT YES ☒ NO ☐

Completed by: S. Diana Hudson Date 1-8-99

.....
where's

FINAL ACTION

Response Code _____

Response Date: / /

M.C.: _____ (1) Cite-All

_____ (4) Not Applicable

_____ (8) Selective

CRP: Yes _____ No _____

Restricted Use: Yes _____ No ✓

Manufacturing Use: Yes _____ No _____

Exclusive Use: Yes _____ No _____

*Info Support of a
Registration Application*



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

07/10/98

AMY PLATO ROBERTS
SHALDRA INC
1101 17TH STREET, N.W., SUITE 500
WASHINGTON DC 20036

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PRODUCT NAME: OXIDATE BROAD SPECTRUM BACTERICIDE/FUNGICIDE
COMPANY NAME: TECHNO.SCIENCE GRP.FOR BIOSAFE
OPP IDENTIFICATION NUMBER: 263323
EPA FILE SYMBOL: 70299-E
EPA RECEIPT DATE: 07/07/98

SUBJECT: RECEIPT OF APPLICATION FOR A NEW ME-TOO REGISTRATION

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for a new 'me-too' registration and it has passed an administrative screen for completeness.

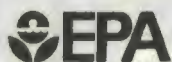
During the initial screen we determined that the application qualifies for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability.

If you have any questions, please contact Marshall Swindell, Product Manager 33, at (703)-308-6230.

Sincerely,

A handwritten signature in cursive script, appearing to read "F. Wince".

Front End Processing Staff
Information Services Branch
Program Management and Support Division



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

263323

Application for Pesticide - Section I

1. Company/Product Number 70299- <i>E</i>	2. EPA Product Manager Ray Sjoberg <i>Ray Sjoberg</i>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Oximate Broad Spectrum Bactericide/Fungicide	PM# Marshall Swindell <i>733</i> 91 / BPPD <i>pnl 90</i>	
5. Name and Address of Applicant (Include ZIP Code) BioSafe Systems 80 Commerce Street Glastonbury, CT 06033 <input checked="" type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 70299-1 Product Name ZeroTol Broad Spectrum Algicide/ Fungicide	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application. 70299-1 ZeroTol Broad Spectrum Algicide/fungicide
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 1, 2.5, 5 & 55 gallon jugs		5. Location of Label Directions <input checked="" type="checkbox"/> container	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Amy Plato Roberts		Title Regulatory Consultant		Telephone No. (Include Area Code) (202) 828-8964	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Regulatory Consultant			
4. Typed Name Amy Plato Roberts		5. Date July 7, 1998			

112

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PW-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). (If not exempted by 40 CFR 152.81 (b) (4));
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PW number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

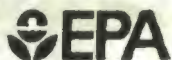
1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, submission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only:



United States
Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0060

Certification with Respect to Citation of Data

Applicants Name and Address
BioSafe Systems
80 Commerce Street
Glastonbury, CT 06033

EPA File Symbol/Registration Number
70299-*E*

Product Name Oxidate Broad Spectrum Bactericide/Fungicide

Date of Application July 7, 1998

NOTE: If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application. (Check the appropriate boxes, in items 2 and 3, or 4 below that pertain to your application.)

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study.

☐ I am the original submitter*; or

☐ I have obtained the written permission of the original submitter for _____, which is
(insert name of chemical)
_____ (for multiple chemicals link the companies who are original data submitters
(insert names of companies)
with the appropriate chemical name) to cite that study*

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study;

a. ☒ I am the original data submitter*; or

☐ I have obtained the written permission of the original data submitter for _____, which is
(insert name of chemical)
_____ (for multiple chemicals link the companies who are original data submitters
(insert names of companies)
with the appropriate chemical name) to cite that study*; or

b. ☐ I have notified in writing the companies _____ for _____ that
(insert names of companies) (insert name of chemical)

have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(F) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are:

Companies _____ for _____ (for multiple
(insert names of companies) (insert name of chemical)
chemicals link the companies who are original data submitters with the appropriate chemical name)
listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method*). (Also, sign the General Offer Statement below.)
Companies _____ for _____ (for multiple
(insert names of companies) (insert name of chemical)
chemicals link the companies who are original data submitters with the appropriate chemical name)
that have submitted the studies which I have cited (Selective method*).

4. ☐ I certify that for each study cited in support of this application I am not required to offer data compensation or obtain written permission because all time periods for exclusive use and data compensation have expired.

*A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method)

Signature  Name and Title Amy Plato Roberts, Regulatory Consultant Date July 7, 1998

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required.

Signature _____ Name and Title _____ Date _____

DATA MATRIX

1. PRODUCT NAME Oxidate™ Broad Spectrum Algicide/Fungicide		2. EPA REG. NO/FILE SYMBOL 70299- <i>E</i>		3. FORMULATORS EXEMPTION SELECTED YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>		4. PAGE 1 OF 3		
5. APPLICANT'S NAME AND ADDRESS BioSafe Systems 80 Commerce Street Glastonbury, CT 06033		6. APPLICATION FOR REGISTRATION DATED 7/7/98		7. NAME OF ACTIVE INGREDIENT(S): <i>Hydrogen Peroxide</i>				
8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT						10. MRID NUMBER, EPA ASCENSION NUMBER OR OTHER EPA IDENTIFYING NUMBER
8a. Regulation Part / Guideline Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by Another Person/ Firm (Name)	9d. Certification of Permission (P) or Offer to Pay (OTP) Enclosed. Indicate "P" or "OTP"	9e. Public Literature	9f. N.A. or Waiver or Other (Explain)	
OPPTS 830.1550	Product Identity and Composition	yes	9/12/96					441160-01
OPPTS 830.1600	Description of Materials Used to	yes	9/12/96					441160-01
OPPTS 830.1650	Description of Formulation Process	yes	9/12/96					441160-01
OPPTS 830.1670	Discussion of Formation of Impurities	yes	9/12/96					441160-01
OPPTS 830.1700	Preliminary Analysis	yes	9/12/96					441160-02
OPPTS 830.1750	Certified Limits	yes	9/12/96					441160-02
OPPTS 830.1800	Enforcement Analytical Method	yes	9/12/96					441160-02
OPPTS 830.1900	Submission of Samples						n.a.	
OPPTS 830.6303	Physical State	yes	6/17/97					443401-01
OPPTS 830.6314	Oxidizing/Reducing Action	yes	6/17/97					443402-01

DATA MATRIX

1. PRODUCT NAME Oxdate™ Broad Spectrum Algicide/Fungicide		2. EPA REG. NO/FILE SYMBOL 70299- E		3. FORMULATORS EXEMPTION SELECTED YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>			4. PAGE 2 OF 3	
5. APPLICANT'S NAME AND ADDRESS BioSafe Systems 80 Commerce Street Glastonbury, CT 06033		6. APPLICATION FOR REGISTRATION DATED 7/7/98		7. NAME OF ACTIVE INGREDIENT(S): Hydrogen Peroxide				
8a. Regulation Part / Guideline Number	8b. Name of Test	9. SOURCE OF DATA SATISFYING REQUIREMENT						10. MRID NUMBER, EPA ASCENSION NUMBER OR OTHER EPA IDENTIFYING NUMBER
		9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by Another Person/ Firm (Name)	9d. Certification of Permission (P) or Offer to Pay (OTP) Enclosed. Indicate "P" or "OTP"	9e. Public Literature	9f. N.A. or Waiver or Other (Explain)	
OPPTS 830.6315	Flammability	yes	6/17/97					443402-01
OPPTS 830.6316	Explodability	yes	6/17/97					443402-01
OPPTS 830.6317	Storage Stability	yes	6/17/97					443402-01
OPPTS 830.6319	Miscibility	yes	6/17/97					443402-01
OPPTS 830.6320	Corrosion Characteristics	yes	6/17/97					443402-01
OPPTS 830.6321	Dielectric Breakdown Voltage	yes	6/17/97					443402-01
OPPTS 830.7000	pH	yes	6/17/97					443402-01
OPPTS 830.7100	Viscosity	yes	6/17/97					443402-01
OPPTS 830.7300	Bulk Density	yes	6/17/97					443402-01

DATA MATRIX

1. PRODUCT NAME Oxidate™ Broad Spectrum Algicide/Fungicide		2. EPA REG. NO/FILE SYMBOL 70299- <i>E</i>		3. FORMULATORS EXEMPTION SELECTED YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>		4. PAGE 3 OF 3		
5. APPLICANT'S NAME AND ADDRESS BioSafe Systems 80 Commerce Street Glastonbury, CT 06033		6. APPLICATION FOR REGISTRATION DATED 7/7/98		7. NAME OF ACTIVE INGREDIENT(S): <i>Hydrogen Peroxide</i>				
8a. Regulation Part / Guideline Number	8b. Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by Another Person/ Firm (Name)	9d. Certification of Permission (P) or Offer to Pay (OTP) Enclosed. Indicate "P" or "OTP"	9e. Public Literature	9f. N.A. or Waiver or Other (Explain)	10. MRID NUMBER, EPA ASCENSION NUMBER OR OTHER EPA IDENTIFYING NUMBER
870.1100	Acute Oral Toxicity	yes	9/12/96					441160-05
870.1200	Acute Dermal Toxicity	yes	9/12/96					441160-05
870.1300	Acute Inhalation Toxicity	yes	9/12/96					441160-05
870.2400	Primary Eye Irritation	yes	9/12/96				→	441106-05
870.2500	Primary Dermal Irritation	yes	9/12/96					441106-05
870.2600	Dermal Sensitization	yes	9/12/96					441106-05

B



WASHINGTON

1101 17th Street, N.W.
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Telephone 202 223-4392
Fax 202 872-0745

Roy Sjoblad
Biochemicals Branch
Biopesticide and Pollution Prevention Division
Office of Pesticide Programs
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

July 7, 1998

RE: Application for "Me-too" Registration of Oxidate™ Broad Spectrum Bactericide / Fungicide for the control of plant pathogenic diseases on food crops (active ingredient: Hydrogen peroxide 27%)

SAN FRANCISCO

2700 Steuart Street Tower
One Market
San Francisco, CA 94105
Telephone 415 267-4119
Fax 415 267-4198

Dear Mr. Sjoblad:

Technology Sciences Group, on behalf of BioSafe Systems, submits the enclosed application for registration of **Oxidate™ Broad Spectrum Bactericide / Fungicide** for the control of plant pathogenic diseases on food crops. Enclosed you will find the following in support of this application:

- 1) Application form (*OPP Identifier Number 263323*);
- 2) Confidential Statement of Formula;
- 3) Certification with Respect to Citation of Data form;
- 4) Data Matrix Table;
- 5) Five (5) copies of the product label.

SACRAMENTO

712 Fifth Street
Suite A
Davis, CA 95616
Telephone 530 757-1298
Fax 530 757-1299

Oxidate™ is identical to an already registered BioSafe Systems product - ZeroTol™ Broad Spectrum Algaecide/Fungicide, EPA Reg. No. 70299-1. ZeroTol is registered for use to prevent and control plant pathogenic diseases on ornamentals, turf and greenhouse surfaces. The proposed label for **Oxidate™** encompasses the same target pests on growing plants, fruits, nuts and vegetable grown in the field, commercial greenhouses, garden centers, landscapes, nurseries and interiorscapes. A petition for an exemption from the requirement of a tolerance in and on all raw agricultural commodities was submitted on June 24, 1998 to support these uses.

E-mail tsg@tsgusa.com

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As noted in the petition, hydrogen peroxide is currently registered for use as an antimicrobial agent on food crops and processed commodities (EcoLab, Inc.), and an exemption has already been granted for hydrogen peroxide, up to 120 ppm, in or on raw agricultural commodities and in processed commodities, when such residues result from the use as an antimicrobial agent on fruits, vegetables, tree nuts, cereal grains, herbs and spices (40 CFR 180.1197).

SAN FRANCISCO

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San Francisco, CA 94105
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Should you have any questions or comments please let us know.

Sincerely,

Amy Plato Roberts
Regulatory Consultant for BioSafe Systems
(202) 828-8964

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